

Amendments to the Specification

Please replace paragraph [0013], which appears on page 5 of the application as filed, with the following amended paragraph:

[0013] In some configuration, a plurality of steering lumens may be employed in a catheter. For example, a catheter may include a first lumen and a second lumen. The first lumen may ~~[[terminates]]~~ terminate at a first point along the length of the catheter, and the second lumen may terminate at a second point along the length of the catheter. The two termination points may be the same or may be offset. Moreover, the two termination points may be at different points along the circumference of the shaft or tubular body of the catheter. As such, the first lumen and second lumen may cause bends of the catheter at different points along the length of the catheter and in different directions when fluid is introduced into the lumens.

Please replace paragraph [0057], which appears on page 11 of the application as filed, with the following amended paragraph:

[0057] Aspects of the present invention also involve an ablation catheter employing a manifold arrangement along the ablation region for conveying energized ablation fluid to a target tissue. In one particular arrangement, the catheter includes a tubular body defining a curved loop region along the distal end region of the catheter. As such, the loop or, more generally, curved region is in the ablation region of the catheter. The loop region of the implementations discussed herein ~~[[are]]~~ is particularly suited for ablation procedures at a pulmonary vein at the left atrium. However, manifold arrangements discussed herein may be arranged in any number of configurations more suitable for other ablation procedures, ~~[[and as such]]~~ and, as such, the present invention is not intended to be limited to configurations best suited for pulmonary vein ablation. The tubular body includes an ablation fluid supply lumen adapted to provide ablation fluid to the curved ablation region of the catheter. A plurality of manifold arrangements are provided along the loop region of the catheter. The manifolds provide a conduit for directing

ablation fluid from the ablation fluid supply lumen fairly uniformly through each manifold around the loop. The manifold arrangement may be implemented in the steerable and shapable catheter mentioned above which employs an actuating lumen adapted to receive a fluid and change the shape of the catheter. However, the manifolding arrangement may be employed in other catheters that do not incorporate an actuating fluid lumen to alter the shape of the catheter.

Please replace paragraph [0060], which bridges pages 12 and 13 of the application as filed, with the following amended paragraph:

[0060] Fig. 2 illustrates one embodiment of a catheter ablation system 36 with a shapable ablation catheter 38 extending from the distal end portion of a sheath ~~[[40of]]~~ 40 of a guiding introducer. As used herein and commonly used in the art, the term “distal” is used generally to refer to components of the catheter system, such as an ablation region 42 of the catheter 38, that is located or generally orientated toward the heart or other target tissue when the catheter is in use. On the other hand, the term “proximal” is used generally to refer to components or portions of the catheter, such as a connector 44, that are located or generally orientated away from or opposite the heart or other target tissue when the catheter is in use.

Please replace paragraph [0085], which appears on page 22 of the application as filed, with the following amended paragraph:

[0085] The shaping element 64 may be precurved so that the ablation region 42 of the catheter will take on a shape similar to that of the catheter of Figs. 3A-3C when the catheter is moved out of the sheath. In order to change the shape of the ablation region of the catheter after it is pressed out of the sheath, fluid is introduced into the single fluid lumen 84. The fluid fills the lumen and causes pressure to build within the lumen 84 which in turn causes a bending moment against the precurved shaping element 64. Unlike the embodiment including a separate

actuating lumen, the fluid lumen of the embodiment of Figs. 9-11 also carries saline or some other conductive fluid medium to the manifolds 72. The fluid flows through the manifolds to become energized and subsequently convey ablation energy to the target tissue. The shaping element of the catheter of Figs. 9-11 also defines an electrode lumen [[80]] housing an electrode 74 similar to the electrode lumen 80 and electrode 74 of Figs. 5-8. In the catheter implementation of Figs. 9-11, fluid flow into the fluid lumen 84 and through the manifolds must be regulated in order to maintain the appropriate amount of fluid flow to ablate the tissue and also to deflect the catheter the appropriate amount so that the ablation region is located adjacent the target tissue as fluid flows out the ablating outlet ports [[89]] 78.

Please replace paragraph [0087], which bridges pages 22 and 23 of the application as filed, with the following amended paragraph:

[0087] In one particular arrangement, the sensors [[80]] 86 define a sensing section 88 and leads 90 extending from each end thereof. The sensing section is arranged generally parallel to the longitudinal axis of the catheter. The leads extend into the lumen 84 through apertures defined in the shaping element 64. Wires (not shown) may be strung to the leads along the lumen and connected with the connector 44 at the proximal end of the catheter. In the catheter of Figs. 9-11, sensors are arranged on either side of the manifold so that the sensing sections extend generally between adjacent channels. Sensors may be employed in various catheter arrangements conforming to the present invention.

Please replace paragraph [0094], which appears on page 25 of the application as filed, with the following amended paragraph:

[0094] More particularly, Figs. ~~15A, B~~ 15A, 15B, and 16 illustrate side views, and a section view, respectively, of one example of a catheter 38 including an actuating lumen 56 terminating

at some point along the length of the shaft 50. The actuating lumen may terminate at any point between the proximal and distal end of the shaft. In the example of Figs. 15A-16, the catheter is not precurved. Fig. 15B illustrates the catheter of Fig. 15A when fluid is within the actuating lumen. When fluid is introduced into the actuating lumen and the fluid flow is impeded by the terminal distal end of the actuating lumen, a bending force is imparted by the fluid on the shaft. As such, the shaft will bend to some degree along the force line of the bending force.

Please replace paragraph [0095], which bridges pages 25 and 26 of the application as filed, with the following amended paragraph:

[0095] ~~Figs. 17A, B and 18 illustrated~~ 17A, 17B, and 18 illustrate side views, and a section view, respectively, of one example of a catheter 38 including a plurality of actuating lumens 56, in this example four actuating lumens, terminating at some point along the length of the shaft 50. The actuating lumens may terminate at any point between the proximal and distal end of the shaft. Moreover, any of the actuating lumens (whether arranged alone or in multiple actuating lumen arrangements) may be arranged anywhere along the circumference of the tubular body shaft. In some implementations, the force imparted by the fluid in the actuating lumen is along a line between the longitudinal axis of the actuating lumen 56 and the longitudinal axis of the catheter shaft 50. For example, Fig. 17B illustrates the catheter of Fig. 17A with fluid introduced into the lower actuating lumen. Here the force is along the line between the lower lumen and the longitudinal axis of the shaft; as such, the catheter is bent upward by the force of the fluid in the lumen.

Please replace paragraph [0097], which appears on page 26 of the application as filed, with the following amended paragraph:

[0097] Figs. 19 and 20 illustrate a catheter 38 employing an interlaced or interwoven electrode strand 100 situated around the outside curve of the ablation region 42 ~~of a catheter configured with a loop 54 at the catheter~~ distal end. Particularly, Fig. 19 is a side view of the distal end region of the catheter, and Fig. 20 is a section view taken along line ~~19-19~~ 20-20 of Fig. 19. An interlaced electrode arrangement, such as is illustrated in Figs. 19-20, may be employed in any type of ablation catheter arrangement, such as a conventional ablation catheter arrangements or any of the ablation catheter arrangements conforming to various aspects of the present invention and discussed herein. Both the elastic electrode arrangement 92 of the ablation catheter of Figs. 12-14 and the interlaced electrode arrangement 100 of the ablation catheter of Figs. 19 and 20 may be employed to provide a continuous or nearly continuous lesion at a target tissue (e.g., a circumferential lesion at or around the inner wall of a pulmonary vein). Moreover, the electrode arrangements of Figs. 12-14 and 19-20 help to isolate ablation energy being directed to the target tissue from the blood around the target tissue.

Please replace paragraph [00100], which bridges pages 27 and 28 of the application as filed, with the following amended paragraph:

[00100] The second interlaced region 110 also defines a plurality of strand sections that are alternatingly arranged outside the catheter and within the lumen. The strand sections of the first interlaced region 106 and the second interlaced region 110 are arranged along the outside of the catheter to work in concert to define a generally continuous section of exposed electrode. As such, the strand is interlaced so that exposed strand sections of the first interlaced section are located adjacent exposed strand sections of the second interlaced section. Having a continuous or nearly continuous exposed electrode along the outer circumference of the loop allows the interleaved electrode strand arrangement to ablate a continuous or nearly continuous lesion along

a section of target tissue. Moreover, being interlaced, the electrode weave may conform to changes ~~change~~ in the curve shape of the catheter.

Please replace paragraph [00111], which bridges pages 31 and 32 of the application as filed, with the following amended paragraph:

[00111] In one particular configuration, the channels are sized to provide little resistance to saline flow, and minimize the diversion of electrical current from the target tissue. In such a configuration, the depth of the channel is about 0.005 inch and the width is about 0.003 inch adjacent the ablating fluid outlet port 78. The channels are defined in the outside circumference of the tubular side wall of the catheter. As such, the channels are curved with the depth of the channel tapered along its length. The deeper ends of the channel ~~[[80]]~~ 82 are adjacent the ablating fluid outlet ports and the depth of the channel lessens as the channel extends away from the ablating fluid ports. From Fig. 23, it can be seen that due to the curvature of the channel, when the catheter is located against target tissue, the channel extends along and away from the target tissue. During a procedure, a portion of at least one channel associated with each ablating port should extend away from the target tissue. As such, a path for fluid to flow away from the electrode 74 is provided. In addition, the depth of the channel is larger than the width, which helps to prevent tissue from deforming into the channel and occluding the manifold when the ablation region is pressed into or situated against target tissue.

Please replace paragraph [00112], which appears on page 32 of the application as filed, with the following amended paragraph:

[00112] In some embodiments discussed herein, radiopaque tip markers are provided at the end of the catheter or along the length of the catheter so that a physician may track the progress of the catheter en route to target tissue and the placement of the catheter at the target tissue. In

the ablation catheter of Figs. 22-23, a coiled spring 118 is located ~~with~~ within the fluid lumen 70 generally along the ablation region 42 of the catheter. In some examples, the coiled spring may be fabricated of platinum, tantalum, gold, stainless steel, gold-plated stainless steel, and the like to provide radiopacity.

Please replace paragraph [00114], which bridges pages 32 and 33 of the application as filed, with the following amended paragraph:

[00114] Figs. 25 and 26 depict one ablation catheter according to the present invention while being used to ablate tissue in the left superior pulmonary vein 120. Figs. 25 and 26 include a number of primary components of the heart (also shown in Fig. 1) to orient the viewer. In particular, starting in the upper left hand portion of Figs. 25 and 26 and working around the periphery of the heart in a counterclockwise fashion, the following parts of the heart 10 are depicted: superior vena cava ~~[[24]]~~ 20, right atrium 14 (labeled in Fig. 1), inferior vena cava 22 (labeled in Fig. 1), right ventricle 12, left ventricle 16, left superior pulmonary vein ~~[[94]]~~ 120, left atrium 18, left pulmonary artery 122, arch of aorta 124, and right pulmonary artery 126. The distal portion 54 (labeled in, for example, Figs. 3A and 4A) of the ablation catheter is positioned adjacent to the ostium 34 (labeled in Fig. 1) of the left superior pulmonary vein 120 using known procedures like the "Seldinger technique." For example, to get the distal loop portion 54 of the ablation catheter 38 in the position shown in Fig. 25, the right venous system may be first accessed using the "Seldinger technique," wherein a peripheral vein (such as a femoral vein) is punctured with a needle, the puncture wound is dilated with a dilator to a size sufficient to accommodate an introducer. The introducer with at least one hemostatic valve is seated within the dilated puncture wound while maintaining relative hemostasis. With the introducer in place, the sheath with a dilator and needle housed within the lumen are introduced through the hemostatic valve of the introducer and advanced along the peripheral vein, into the region of the vena cava (e.g., the inferior vena cava 22), and into the right atrium 14. From there, the sheath 40 is further advanced through a hole in the interatrial septum, which a doctor would make using

the needle and dilator. Once the sheath is fit through the interatrial septum and gains access to the left atrium 18, the sheath is positioned generally along the longitudinal axis of one of the pulmonary veins. In Fig. 25, the sheath 40 is shown in alignment with the ~~longitudinal~~ longitudinal axis of the left superior pulmonary vein 120. Positioned as such, the dilator and needle are pulled back through the sheath.

Please replace paragraph [00119], which appears on page 35 of the application as filed, with the following amended paragraph:

[00119] In order to form a sufficient lesion, it is desirable to raise the temperature of the tissue to at least 50°C for an appropriate length of time (e.g., one minute). Besides ablating the tissue, the conductive medium flowing through the ports ~~[[70]]~~ 78 prevents blood from flowing into the ablation catheter and pushes blood from the area adjacent to the ports. This helps prevent coagulum, which can have undesirable effects on the patient. The conductive medium is also caused to flow at a rate that prevents the electrode from overheating the conductive medium producing vapor in the fluid lumen 70. Thus, the flow of conductive medium through the fluid lumen and out the ports is managed or regulated so that there is sufficient flow to prevent vaporization, but not so much flow that the electrode is prohibited from sufficiently heating the fluid to form a desired lesion. Also, if too much conductive medium flows out of the ports, the hemodynamics of the patient may be adversely affected by the excess quantity of conductive medium being mixed with the patient's blood. The desired flow rate is achieved by adjusting the pressure driving the conductive medium through the fluid lumen, the diameter of the ports, and the spacing between the ports.

Please replace paragraph [00121], which appears on page 36 of the application as filed, with the following amended paragraph:

[00121] In the example of an ablation catheter that includes a partially precurved shaft and a shaping element, upon exiting the sheath, the catheter forms a first loop shape. By introducing fluid into the actuating lumen 56, the loop may be expanded, i.e., the diameter of the loop increased, so that the ablation region may be expanded to ~~[[contract]]~~ contact the walls of a vein or the like. To retract the ablation catheter, the fluid pressure in the actuating lumen is lessened to decrease the loop size and withdraw the ablation catheter out of the vein.

Please replace paragraph [00122], which appears on page 36 of the application as filed, with the following amended paragraph:

[00122] Although preferred embodiments of this invention have been described above with a certain degree of particularity, those skilled in the art could make numerous alterations to the disclosed embodiments without departing from the spirit or scope of this invention. All directional references (e.g., upper, lower, upward, downward, left, right, leftward, rightward, top, bottom, above, below, vertical, horizontal, clockwise, and counterclockwise) are only used for identification purposes to aid the reader's understanding of the present invention, and do not create limitations, particularly as to the position, orientation, or use of the invention. Joinder references (e.g., attached, coupled, connected, and the like) are to be construed broadly and may include intermediate members between a ~~[[connection]]~~ collection of elements and relative movement between elements. As such, joinder references do not necessarily infer that two elements are directly connected and in fixed relation to each other. It is intended that all matter contained in the above description or shown in the accompanying drawings shall be interpreted as illustrative only and not limiting. Changes in detail or structure may be made without departing from the spirit of the invention as defined in the appended claims.